REMARKS

Applicant has carefully reviewed the final Office Action mailed November 29, 2007 and offers the following remarks to accompany the above amendments.

Status of the Claims

Claims 1, 5, 7, 9, 11-15, 17-20, 22, 24, and 26-45 are pending in the present application.

Claims 2-4, 6, 8, 10, 16, 21, 23, and 25 were previously cancelled.

Claims 26-45 were previously withdrawn.

Claims 1, 7, and 9 have been amended to provide that the human subject is instructed on the moment to breathe as opposed to providing an indication. As will be discussed below with respect to Stabler, Applicant intended the term "indicating" to encompass instructing the human subject, but this amendment has been made to alleviate any differences in interpretation. This amendment should be entered as it does not constitute grounds for a new search.

The "Claimed Invention"

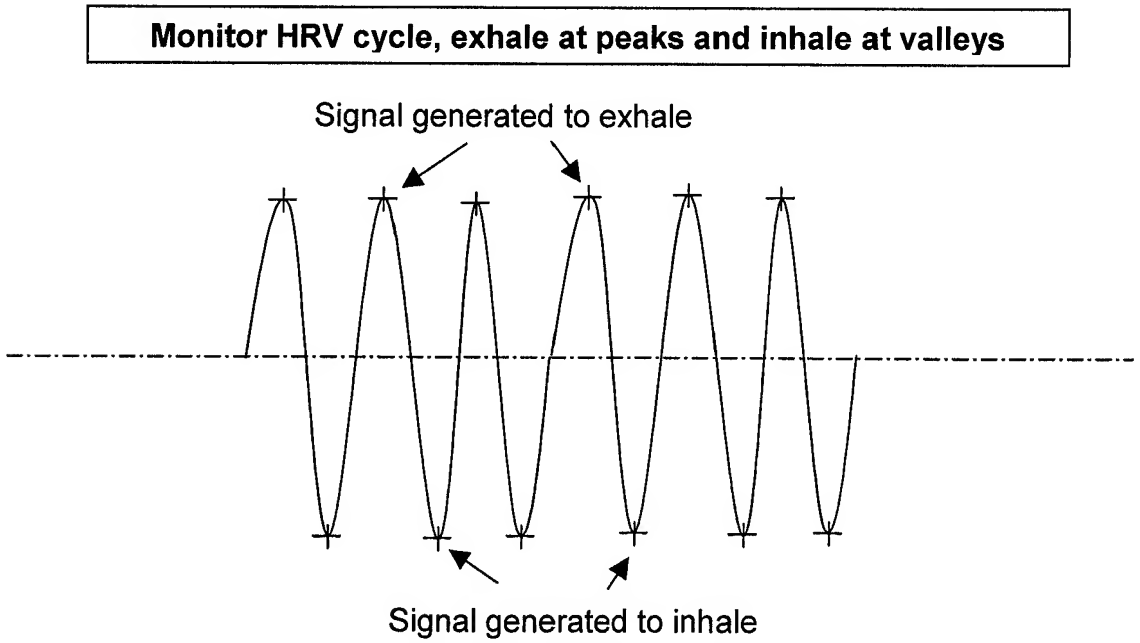
Before addressing the rejections, Applicant believes it would be beneficial to explain the claimed invention and its goals, as well as examples of such.

The goal of Applicant's invention is to facilitate maximization of coherence of a patient's heartbeat rate variability (HRV). HRV is the variation in periodicity and amplitude of the natural heartbeat rate over time. An irregular or inconsistent HRV is typically associated with physiological and emotional stress. On the other hand, a more consistent HRV is typically associated with physiological harmony. A highly coherent HRV results in a level of consistency in periodicity and amplitude of the natural heart beat rate cycle over time. Hence, the use of the term "coherence." "Coherence" is achieving a level of consistency in a patient's HRV to reduce or improve physiological harmony and emotional stress. The goal of the claimed invention is to instruct the patient on how to breathe to achieve coherence.

As discussed in paragraph 0007 of the Specification, the inventor recognized that although a heart beat rate cycle has its own natural variable rhythm, there is a strong correlation between a heart beat rate cycle and the breathing cycle. This is to say that while the HRV cycle and breathing cycle relationship exists, in untrained subjects, their alignment appears random. As illustrated in Figure 2 of the present application, when the natural heart beat rate cycle and

breathing cycle are misaligned (as shown on the left side of the top graph), the resulting HRV below is highly incoherent. However, when the natural heart beat rate cycle and breathing cycle are aligned, the natural heart beat rate cycle becomes more consistent. This results in a highly coherent HRV, as shown in the bottom graph of Figure 2. Thus, a patient is instructed on how align their breathing cycle with their natural heart beat rate cycle based on the feedback of the heartbeat cycle transitions to achieve greater consistency in a natural heart beat rate cycle and in turn a more coherent HRV.

These concepts are consistent with the claimed invention. In this regard, claim 1 of the application monitors a patient's heartbeat in the time domain. The transitions of the heartbeat rate are presented to the user, which may be in the form of individual audible, visual, or tactile biofeedback signals. The biofeedback signals are presented to the patient in the time domain as individual indications. The biofeedback signals indicate transitions in the natural heart rate from both a maximum and minimum heart rate. The moments of biofeedback indication are illustrated by the exemplary HRV cycle below.



Next, the patient is instructed when to inhale and when to exhale to synchronize their breathing with their heartbeat cycle as indicated by the indicators to inhale and exhale. In this manner as discussed above, as the patient's heartbeat rate cycle and breathing cycle become aligned, the heartbeat rate cycle becomes more consistent. Thus, HRV becomes more coherent. The

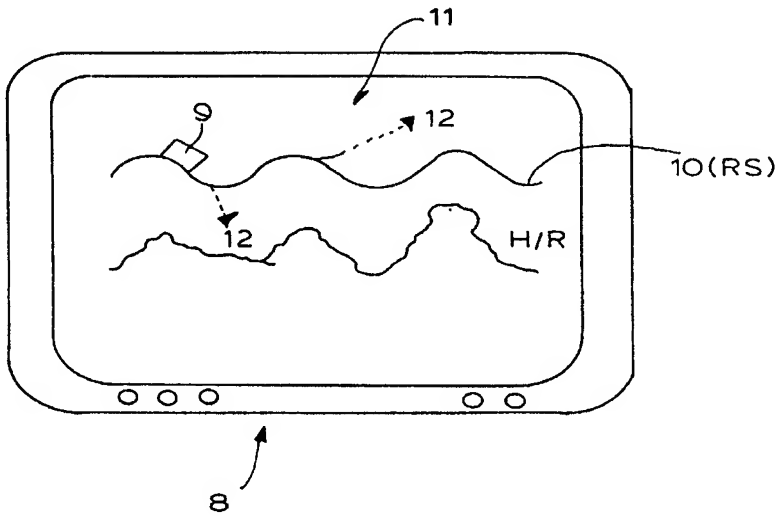
biofeedback signals presented to the user are in the time domain, because these biofeedback signals are used to instruct the patient on how to breathe in the time domain.

Rejection under 35 U.S.C. § 102(b) - Vaschillo

The Patent Office continues to maintain a rejection of claims 1, 3, 5, 7, 9, 11-15, 17-20, 22, and 24 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,997,482 to Vaschillo et al. (hereinafter "Vaschillo"). Applicant respectfully traverses. For the Patent Office to prove anticipation, each and every element of the claims must be present in the reference. Furthermore, the elements of the reference must be arranged as claimed. MPEP § 2131.

Vaschillo fundamentally differs from the claimed invention. Vaschillo does not instruct a patient to breathe based on biofeedback signals indicating transitions in the heartbeat rate like the claimed invention. Instead, Vaschillo is simply a monitoring system. Vaschillo's goal is to determine the frequency of resonance of a patient's heart for analysis, not instruction. Resonance is where a patient's breathing cycle aligns with their heartbeat cycle. Vaschillo does this by instructing a patient to breathe in alignment with a reference signal (RS). This is illustrated in Figure 2, which is also shown below. The reference signal (RS) is not a biofeedback of the patient's heartbeat rate, but is instead a predetermined signal at one possible breathing cycle frequency. (Vaschillo, col. 6, ll. 52-55) The patient is instructed to breathe according to the reference signal (RS) on a display (8). The patient is informed whether their breathing is in accordance with the reference signal (RS) (H/R signal in Figure 2).

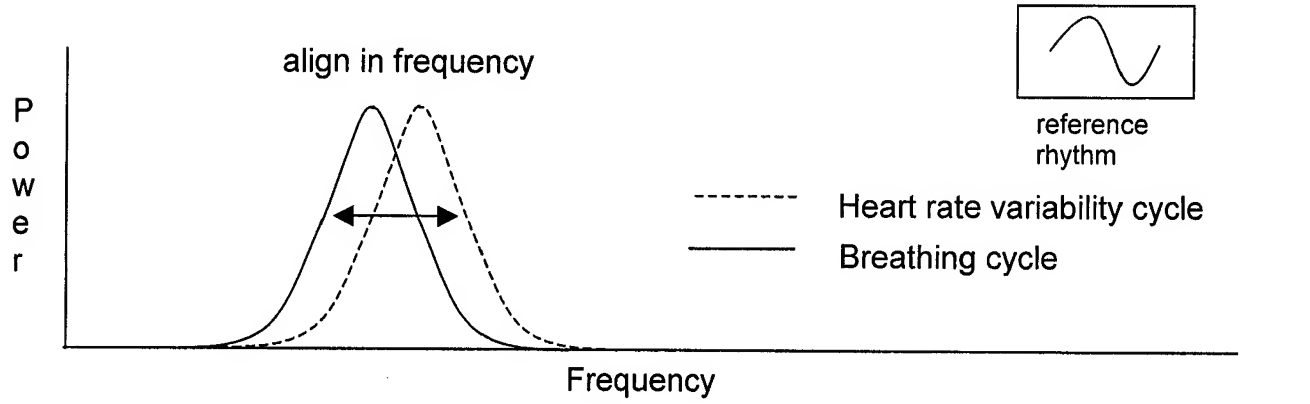
FIG. 2



Vaschillo then records the patient's heartbeat cycle that results from the patient breathing at the reference signal (RS) frequency. Vaschillo then repeats these steps over a series of varied reference signal (RS) frequencies in a sweeping fashion. This data is then analyzed to determine at which reference signal (RS) frequency, the patient's breathing aligns (i.e. resonates) with their heartbeat cycle. Phase shift differences between the reference signal (RS) frequency and the patient's heat rate are analyzed in the frequency domain to determine resonance, or lack therof. Zero phase shift represents resonance. Figures 4A-4B illustrate this data recordation and analysis.

On the contrary, the claimed invention is not a tool to quantify resonance based on theoretical breathing reference signals like in Vaschillo. The claimed invention instructs the patient on the actual breathing cycle required to achieve coherence. The claimed invention provides an instruction signal based on actual biofeedback from the patient's heartbeat cycle. Vaschillo does not. Vaschillo is designed to analyze the patient's heartbeat. The claimed invention is designed to instruct the patient on how to achieve coherence regardless of the current state of the patient's heart. Vaschillo analyzes, whereas the claimed invention instructs and achieves.

A further, but related distinction lies in the fact that Vaschillo performs its analysis in the frequency domain. The claimed invention is not analyzing data in the frequency domain, because the claimed invention is not analyzing at what breathing frequency, the patient's heartbeat is resonant. The claimed invention is instructing the patient on how to breathe to reach coherence regardless of the current state of the patient's heart. This distinction is illustrated in the drawing below. This drawing represents Vaschillo's operation, wherein a phase difference is measured between the patient's heartbeat and their breathing cycle to determine resonance, or lack thereof.



Goal: Identify exact frequency of resonance

Frequency at which alignment occurs is exact frequency of resonance

Applicant respectfully submits that Vaschillo does not anticipate claim 1. Claims 5, 7, 9, 11-15, 17-20, 22, and 24 depend, either directly or indirectly, from claim 1. Accordingly, the rejection of claims 5, 7, 9, 11-15, 17-20, 22, and 24 should be withdrawn for at least the same reasons.

Rejection under 35 U.S.C. § 103(a) – Stabler et al.

Claims 1, 3, 5, 7, 9, 11-15, 17-20, and 22 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,836,681 B2 to Stabler et al. (hereinafter "Stabler"). Applicant respectfully traverses. For the Patent Office to establish *prima facie* obviousness, the Patent Office must show where each and every claim element can be found in the reference. MPEP § 2143.03.

Applicant has amended claim 1, the independent claim from among the rejected claims, to provide that the human subject is instructed on when to breathe. Specifically, the human subject is instructed on the moment to inhale and exhale based on the biofeedback signal indicating the transitions in the subject's heart beat cycle. This amendment is made in response to the Examiner's comments regarding the claims in light of Stabler on page 2 of the final Office Action mailed on November 29, 2007.

Stabler does instruct a human to breathe at a target rate based on biological feedback sensors attached to the patient (i.e. human) (col. 2, ll. 35-38). Stabler simply displays a graph of heart rate variability and amplitude of breathing to the patient to indicate to the patient whether the HRV and breathing cycles are synchronized in a feedback fashion. However, Stabler does not teach or suggest that the instructions include when to inhale and exhale based on transitions in the natural heart beat rate cycle like that provided in the claimed invention. It is left up to the patient to determine when to inhale and exhale. The patient is simply given the results to indicate if the patient is in the "zone" without any real understanding of the relationship of inhalations and exhalations to transitions in the natural heart beat rate cycle (col. 4, ll. 1-17). Stabler simply requires the patient to continue breathing in a controlled fashion until the patient

gets it right and reaches the "zone." A breakthrough in the Applicant's invention is the recognition of inhalation and exhalation in breathing cycle to coherence and instructing the patient specifically at the transition times as to when to inhale and exhale. Thus, Stabler does not render the claimed invention obvious, and thus this rejection must be withdrawn.

Claims 5, 7, 9, 11-15, 17-20, and 22 depend, either directly or indirectly, from claim 1. Accordingly, the rejection of claims 5, 7, 9, 11-15, 17-20, and 22 should be withdrawn for at least the same reasons as claim 1. Applicant respectfully submits that claims 1, 5, 7, 9, 11-15, 17-20, and 22 are in condition for allowance and notice of the same is requested at the earliest possible date.

Conclusion

The present application is now in condition for allowance and such action is respectfully requested. The Examiner is encouraged to contact Applicant's representative regarding any remaining issues in an effort to expedite allowance and issuance of the present application.

Respectfully submitted,

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